

**Translation**

Rec'd PCT/PTO 19 JAN 2005  
PCT/JP2003/009324

PATENT COOPERATION TREATY



# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|   |  |  |
|---|--|--|
| Applicant's or agent's file reference<br><b>M1-A0201Y1P</b>   | <b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416                                |  |
| International application No.<br><b>PCT/JP2003/009324</b>   | International filing date (day/month/year)<br><b>23 July 2003 (23.07.2003)</b> | Priority date (day/month/year)<br><b>23 July 2002 (23.07.2002)</b> |
| International Patent Classification (IPC) or national classification and IPC<br><b>A61K 31/721, A61P 1/04, 31/00, 37/04, 37/08, 43/00</b> |  |  |
| Applicant<br><b>MEIJI DAIRIES CORPORATION</b>   |  |  |

|  |  |
|--|--|
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |  |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>   |  |

|   |  |
|---|--|
| Date of submission of the demand<br><b>30 January 2004 (30.01.2004)</b> | Date of completion of this report<br><b>21 May 2004 (21.05.2004)</b> |
| Name and mailing address of the IPEA/JP                                 | Authorized officer   |
| Facsimile No.   | Telephone No.  |

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/009324

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 7-10

because:

☒ the said international application, or the said claims Nos. 7-10  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The inventions of claims 7-10 concern a method for treating the human body by therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 7-10

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the  
Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with  
the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ see Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/09324

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

|                               |        |            |     |
|-------------------------------|--------|------------|-----|
| Novelty (N)                   | Claims | 11-13      | YES |
|                               | Claims | 1-6        | NO  |
| Inventive step (IS)           | Claims |            | YES |
|                               | Claims | 1-6, 11-13 | NO  |
| Industrial applicability (IA) | Claims | 1-6, 11-13 | YES |
|                               | Claims |            | NO  |

**2. Citations and explanations (Rule 70.7)**

Document 1) JP 51-41083 A

Based on the description in document 1 cited in the international search report, the inventions of claims 1-6 lack novelty and an inventive step. Document 1 states that poly-phosphorylated esters of dextran induce interferon, and that they can be used as a drug. The poly-phosphorylated esters of dextran are one and the same as the phosphorylated dextran referred to in the inventions of this application, and therefore the inventions of claims 1-6 are either identical to those described in document 1, or they can easily be conceived of by persons skilled in the art based on the description in document 1.

Based on the description in document 1 cited in the international search report, the inventions of claims 11-13 lack an inventive step. Document 1 describes the poly-phosphorylated esters of dextran, i.e., phosphorylated dextran, obtained by heating and reacting together dextran and polyphosphoric acid in dimethyl formamide. The method of the inventions of claims 11 and 12 differs from the description in document 1 because the reaction is carried out in formaldehyde solution, and the composition of the inventions of claim 13 differs from the description in document 1 because the phosphorylated dextran is prepared by a method involving a process step using phosphate buffer and a process step in which the reaction solution is lyophilized. However, the use of formaldehyde as a reaction solvent per se and the use of the above various process steps per se are matters that can be selected by persons skilled in the art as needed, and this examination finds that no particularly advantageous effect such as a prominent enhancement of the phosphoric acid content of the phosphorylated dextran obtained or a prominent enhancement of the interferon inducing capability is obtained by adopting these process steps.